

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:  
Dirk M. Anderson and  
Laurent Galibert

Docket No.: 2852-E

Serial No: --to be assigned--

Previous Group Art Unit: 1642

Filed: May 25, 2001

Previous Examiner: E. Lazar-Wesley

For: ANTIBODIES AGAINST LIGAND FOR RECEPTOR ACTIVATOR OF NF- $\kappa$ B

**PRELIMINARY AMENDMENT**

BOX PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, DC 20231

Before examining the above-identified patent application, please enter the following amendments:

In the Title:

Please amend the title of the application as follows:

--ANTIBODIES AGAINST LIGAND FOR RECEPTOR ACTIVATOR OF NF- $\kappa$ B.--

In the Specification:

At page 1, after the heading "CROSS-REFERENCE TO RELATED PATENT APPLICATIONS", please delete the entire paragraph at lines 5-7 and substitute therefor:

-- This application is a divisional of USSN 09/577,780, filed May 24, 2000, which is a divisional of USSN 08/995,659, filed December 22, 1997, now U.S. Patent No. 6,242,213, which claims the benefit of USSN 60/064,671, filed October 14, 1997, USSN 60/077,181, filed March 7, 1997 (filed originally as USSN 08/813,509), and USSN 60/059,978, filed December 23, 1996 (filed originally as USSN 08/772,330). --

At page 3, beginning at line 9, please delete the paragraph beginning with "Figure 4."

At page 3, line 13, please delete the sentence beginning with "Figure 5."

In the Drawings:

Please cancel Figure 4.

Please cancel Figure 5.

In the Claims:

Please cancel claims 1-35.

Please enter the following new claims:

--36. An antibody that is immunoreactive with a RANKL polypeptide as shown in SEQ ID NO:13.

37. An antibody according to claim 36, which is a monoclonal antibody.

38. A method for preparing an antibody according to claim 36, wherein the antibody is elicited by immunizing with a RANKL polypeptide selected from the group consisting of:

- a) a polypeptide comprising amino acids 1-317 of SEQ ID NO:13;
- b) a polypeptide comprising amino acids 69-313 of SEQ ID NO:13;
- c) a polypeptide comprising amino acids 1-162 of SEQ ID NO:13;
- d) a polypeptide comprising amino acids 162-313 of SEQ ID NO:13;
- e) a polypeptide comprising amino acids 138-317 of SEQ ID NO:13;
- f) a polypeptide comprising amino acids x to y of SEQ ID NO:13, wherein x is an amino terminal amino acid between 69 and 162 of SEQ ID NO:13, and y is a carboxy terminal amino acid between 313 and 317 of SEQ ID NO:13
- g) a polypeptide encoded by a nucleic acid molecule that is capable of hybridizing under stringent conditions to a DNA having a nucleotide sequence as shown in SEQ ID NO:12 or its complement, wherein stringent conditions comprise hybridizing in 6 X SSC at 63°C and washing in 3 X SSC at 55°C.

39. An antibody that is immunoreactive with a RANKL polypeptide as shown in SEQ ID NO:11.

40. An antibody according to claim 39, which is a monoclonal antibody.

41. A method for preparing an antibody according to claim 39, wherein the antibody is elicited by immunizing with a RANKL polypeptide selected from the group consisting of:

- a) a polypeptide comprising amino acids 1-294 of SEQ ID NO:11;
- b) a polypeptide comprising amino acids 139-294 of SEQ ID NO:11;
- c) a polypeptide comprising amino acids 1-139 of SEQ ID NO:11;
- d) a polypeptide comprising amino acids 119-294 of SEQ ID NO:11;
- e) a polypeptide comprising amino acids x to y of SEQ ID NO:11, wherein x is an amino terminal amino acid between 48 and 139 of SEQ ID NO:11, and y is a carboxy terminal amino acid between 290 and 294 of SEQ ID NO:11; and
- f) a polypeptide encoded by a nucleic acid molecule that is capable of hybridizing under stringent conditions to a DNA having a nucleotide sequence as shown in SEQ ID NO:10 or its complement, wherein stringent conditions comprise hybridizing in 6 X SSC at 63°C and washing in 3 X SSC at 55°C.--

#### REMARKS

Claims 1-35 have been cancelled from the application, and new claims 36-41 have been added by amendment as indicated above. The title of the application has been amended to more accurately reflect the invention described herein. In addition, the paragraph describing priority has been amended, and Figures 4 and 5 and their corresponding descriptions have been cancelled from the application. These figures are being cancelled because they are not discussed in the specification.

New claims 36-41 relate to antibodies against marine and human RANKL, including a method of making such antibodies. These claims correspond in essence to cancelled claims 31 and 32, thus are supported by the description in these cancelled claims. Support for new claims 36-41 is found throughout the specification, for example, at page 4, lines 16-20; page 4, line 31 to page 5, line 34; page 10, lines 30-36; page 12, lines 5-7; page 18, lines 2-3; Examples 7 and 8, at pages 25-27; Example 10, at pages 27-28; and Example 15, at pages 33-34. Accordingly, these new claims are fully supported in the application and do not constitute the addition of new matter.

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(marked-up version of section of specification amended in Preliminary Amendment)

## ANTIBODIES AGAINST LIGAND FOR RECEPTOR ACTIVATOR OF NF- $\kappa$ B

This application is a [continuation-in-part] divisional of USSN 09/577,780, filed May 24, 2000, which is a divisional of USSN 08/995,659, filed December 22, 1997, now U.S. Patent No. 6,242,213, which claims the benefit of USSN 60/064,671, filed October 14, 1997, [and a continuation-in-part of] USSN 60/077,181, filed March 7, 1997 (filed originally as USSN 08/813,509), [filed March 7, 1997] and [a continuation-in-part of] USSN 60/059,978, filed December 23, 1996 (filed originally as USSN 08/772,330).

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**STATEMENT UNDER 37 CFR 1.821(e)**

BOX PATENT APPLICATION

Assistant Commissioner for Patents

Washington, D.C. 20231

Dear Sir:

Applicant hereby states that no computer readable form of the Sequence Listing is necessary for this application because the sequence listing in the present application is identical to the Sequence Listing submitted for and with the following patent application:

Applicants: Dirk M. Anderson, Laurent J. Galibert and Eugene Maraskovsky  
Serial No.: 08/995,659  
Filed: December 22, 1997  
Title: LIGAND FOR RECEPTOR ACTIVATOR OF NF- $\kappa$ B

In the present application, applicant requests use of the computer readable compliant Sequence Listing already filed for application serial no. 08/995,659 from which immediate parent application, serial no. 09/577,780, itself claims priority. The paper copy of the Sequence Listing of the present application (found on pages 37-68 of the enclosed specification) is identical to the paper copy and the computer readable copy of the Sequence Listing filed on December 22, 1997, in application serial no. 08/995,659. No new matter has been added.

Respectfully submitted,



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